



January 25, 2012

VIA ECF

Honorable Tonianne J. Bongiovanni, U.S.M.J.
U.S. District Court for the District of New Jersey
Clarkson S. Fisher Building & U.S. Courthouse
402 East State Street
Room 6052
Trenton, New Jersey 08608

Re: AstraZeneca AB, et al. v. Hanmi USA, Inc., et al.
Civil Action No. 11-cv-00760 (JAP)(TJB)

John E. Flaherty
Partner
T. 973.639.7903
F. 973.297.3971
jflaherty@mccarter.com

Dear Judge Bongiovanni:

We, along with Fitzpatrick Cella Harper & Scinto, represent Plaintiffs in this matter and submit this letter in reply to Hanmi's January 20, 2012 letter (D.I. 188) opposing AstraZeneca's January 13, 2012 motion (D.I. 182) ("Motion") to strike Hanmi's improperly amended December 9, 2011 invalidity contentions (D.I. 179.10).

Hanmi's claim that its amended contentions add only "about six pages of text [to] Hanmi's original detailed set of contentions" (D.I. 188 at 2, emphasis in original) is only half the story. In addition to those six pages, its amended contentions incorporated a remarkably broad "kitchen sink" catchall suggesting that counsel divine amended contentions from: "all of Hanmi's record positions since the time of serving its initial contentions on May 25, 2011, including summary judgment briefing and supporting evidence, and *Markman* briefing and supporting evidence, including reply and response briefing expected to conclude over the course of the next month." (D.I. 179.10 at 3). As explained in AstraZeneca's Motion (at 1-2), Hanmi's amended contentions therefore incorporate *hundreds of pages* of briefing, new expert opinions and documentary evidence (purportedly including those *not yet briefed* at the time), and set forth new invalidity contentions not previously disclosed in its initial contentions. (For example, Hanmi can point to only a single sentence in its original contentions, which simply identifies its esomeprazole strontium product, in support of its assertion that it had properly provided AstraZeneca with notice of a defense of lack of written description based on hydrates (D.I. 188 at 3) while Hanmi's summary judgment motion no. 4 at pages 7-11 (D.I. 116) relies upon Exh. Nos. 22, 26-28 to the Declaration of Renita S. Rathinam (D.I. 112.13, 112.17-112.19) as well as an expert declaration of Wayne K. Genck, Ph.D. at ¶¶ 79-89 (D.I. 108)).

As explained below, Hanmi's contention amendments directed at claims other than 3, 5 and 10 of the '504 patent were inappropriate, were not ordered by the Court and therefore violate Local Patent Rule 3.7 and should be stricken.

McCarter & English, LLP
Four Gateway Center
100 Mulberry Street
Newark, NJ 07102-4056
T. 973.622.4444
F. 973.624.7070
www.mccarter.com

BOSTON

HARTFORD

NEW YORK

NEWARK

PHILADELPHIA

STAMFORD

WILMINGTON

Hon. Tonianne J. Bongiovanni, U.S.M.J.
01/25/2012
Page 2

AstraZeneca's addition of '504 patent claims 3, 5 and 10 does not justify Hanmi's amendments pertaining to other claims

Hanmi asserts that its contentions pertaining to other claims "required adjustment in view of the new claims." (D.I. 188 at 3). But, claims 3, 5 and 10 were always part of the '504 patent, and Hanmi had no trouble providing 144 pages of noninfringement and invalidity contentions *before* claims 3, 5 and 10 were asserted by AstraZeneca. And, claims 3, 5, and 10 have never been part of the '192 patent. Hanmi has never explained how addressing claims 3, 5 and 10 of the '504 patent now "requires" the incorporation of hundreds of additional pages of arguments and evidence relating to other claims of the '504 and '192 patents.

The Court's order permitting the addition of '504 patent claims 3, 5 and 10 did not permit Hanmi's amendments pertaining to other claims

Hanmi justifies its amendments by stating that when the Court granted AstraZeneca's motion to add claims 3, 5 and 10 to the case, the Court also granted Hanmi the right to amend its contentions with regard to the other claims that were already in the litigation. However, the parties previously agreed that the Court's order did *not* permit Hanmi's amendment to be broader than addressing claims 3, 5, and 10 when they negotiated the Court-ordered schedule governing the exchange of amended contentions. Pursuant to the November 14, 2011 Court Order (D.I. 139), AstraZeneca proposed a schedule for the parties to "address claims 3, 5 and 10 of the '504 patent." Hanmi responded by revising the proposed order to purportedly broaden it to "addres[s] the assertion of claims 3, 5, and 10." AstraZeneca rejected that proposed revision and the parties agreed to submit the proposed order limiting Hanmi's amended contentions to "addressing claims 3, 5 and 10". This is the language in the applicable order. See, Exhibit E (correspondence between parties from November 29, 2011 – November 30, 2011); D.I. 145 (December 1, 2011 Court Order).

Hanmi points to language in the Court's November 14, 2011 Memorandum Opinion suggesting that Hanmi would need to "invest additional resources in evaluating claims 3, 5 and 10 of the '504 patent and that the inclusion of these claims in this matter will likely also require Hanmi to adjust [its] case strategy going forward." (D.I. 138 at 14). Hanmi interprets this comment to mean that the Court "ordered and permitted" Hanmi to supplement its contentions not only by adding contentions directed to the newly added claims 3, 5 and 10 but also by amending contentions directed to the originally asserted claims in both the '504 patent and the '192 patent. (D.I. 188 at 3, emphasis in original). Hanmi has not, and cannot, demonstrate that the statement directed at evaluating claims 3, 5 and 10 invited wholesale amendments of all its contentions, let alone amendment by catchall reference to any contention they have made or may make elsewhere in the case.

Hon. Tonianne J. Bongiovanni, U.S.M.J.
 01/25/2012
 Page 3

Hanmi should not be allowed to circumvent Local Patent Rule 3.7 simply by filing summary judgment motions

From the outset, Hanmi has attempted to do an end-around the Local Patent Rules by pressing summary judgment motions. Hanmi asserts that its wholesale incorporation of summary judgment filings was “directed to conforming Hanmi’s contentions to the case record.” (D.I. 188 at 2). But such filings are not a substitute for the requirements of the local rules. Hanmi was clearly aware of the contentions it intended to raise and should have identified such contentions in its initial invalidity contentions. Hanmi cannot unilaterally amend its contentions by, *inter alia*, filing summary judgment motions, without first satisfying Local Patent Rule 3.7 which requires Hanmi to seek leave of the Court and demonstrate good cause to amend. Local Patent Rule 3.7 explicitly states that “[t]he duty to supplement discovery responses under Fed. R. Civ. P. 26(e) does not excuse the need to obtain leave of Court to amend contentions. . . .”¹ And, Hanmi’s suggestion that a party is not required to adhere to Local Patent Rule 3.7 if it files dispositive motions on new defenses, or amends pleadings to raise new defenses, has already been held improper by this Court.² Opinion and Order in *Hoffmann-La Roche Inc. v. Apotex Inc.*, CA No. 07-4417, D.I. 397 (D.N.J. Dec. 29, 2011).

Hanmi also claims the local patent rules do not apply because AstraZeneca filed oppositions to Hanmi’s summary judgment motions. AstraZeneca did respond to each of Hanmi’s October 11, 2011 summary judgment motions. This does not provide any support for the position that our local rules for the orderly progression of patent cases do not apply. The fact remains that Hanmi never sought leave to amend its contentions so as to make its new positions part of this case and that when it tried to circumvent the rules to do so, it provided a non-specific catch-all incorporation by reference to contentions past, present and future. *Hoffmann-La Roche*, CA No. 07-4417, D.I. 397 (striking new contentions presented in an amended answer as required by F.R.C.P. 6(b)).

¹ See *also*, the Local Civil and Criminal Rules of the U.S. District Court for the D.N.J. (March 18, 2011 Revisions) at 33 (“Report of the Local Patent Rules Committee: Explanatory Notes for the 2011 Amendments”) (“In an effort to avoid potential misunderstandings as to the scope of permitted amendments to obligations under the Local Patent Rules, the Committee sought to clarify that amendments apply to all filings with the Court or exchanges between the parties as may be required by the Local Patent Rules. The proposed rule also makes plain that any amendments require the approval of the Court, notwithstanding consent by the parties. See L. Pat. R. 3.7.”).

² Hanmi incorrectly asserts that the Court already permitted Hanmi’s new contentions into the case. However, the Court never addressed whether Hanmi’s summary judgment motions contained new contentions that were properly in the case in setting a briefing schedule.

Hon. Tonianne J. Bongiovanni, U.S.M.J.
01/25/2012
Page 4

Conclusion

Despite the clarity of Local Patent Rule 3.7, Hanmi never sought leave from the court to amend its contentions. AstraZeneca respectfully requests the Court strike Hanmi's December 9, 2011 amended contentions to the extent they do not address the newly asserted claims 3, 5 and 10.

Respectfully submitted,

s/John E. Flaherty

John E. Flaherty

cc: Hon. Joel A. Pisano, U.S.D.J. (via ECF)
Counsel of record (via ECF)

Enclosure